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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,554	02/16/2001	Kirk Schnorr	10017.200-US	5362

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EXAMINER	
RAO, MANJUNATH N	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/05/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/784,554	SCHNORR ET AL.	
	Examiner	Art Unit	
	Manjunath N Rao	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,19,20,22-24,28 and 29* is/are pending in the application.

4a) Of the above claim(s) *24 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,19,20,22,23 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-12, 19-20, 22-24, 28-29 are still at issue and are present for examination.

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-12, 19-20, 22-23 and 28 in Paper No. 13 is acknowledged. The traversal is on the ground(s) that coexamination of all of Groups I and III would not be burdensome to the Examiner. This is not found persuasive because while the searches for the three groups overlap, they are not coextensive. The search for Group III would each require the search of subclass unnecessary for the search of elected Group I. For example, search of Group I would require search of subclass 510/114 and search of Group III would require search of subclass 435/263

The requirement is still deemed proper and is therefore made FINAL.

Claims 24 and 29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 13. As requested by the applicant Examiner will consider rejoining groups I and III after claims of group I become allowable.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. Also acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 19-20, 22-23 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 (upon which claims 2-12, 19-20, 22-23 and 28 depend) recites the phrase "xyloglucanase enzyme belonging to family 44". It is not clear to the Examiner as to how applicants conclude or based on which characteristics (apart from the property that a xyloglucanase cleaves the ß 1,4-glycosidic linkages in the backbone of a xyloglucan and not cellulose) applicants conclude that a given xyloglucanase enzyme "belongs to family 44". A perusal of the specification also does not provide any criteria for classifying the enzyme as a "family 44" enzyme.

Claim 1-12, 19-20, 22-23 and 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 (upon which claims 2-12, 19-20, 22-23 and 28 depend) recites the phrase "xyloglucanase...which exhibits a relative xyloglucanase activity of at least 30% between pH 5 and 8". Comparison of the enzyme activity is not clear to the Examiner. The question that arises is, "30% enzyme activity at pH 5 and 8" is relative to what ? It is not clear whether applicants are comparing the enzyme activity with another known enzyme or the activity of the same enzyme at a different pH range. If so, until such comparative data are recited in the claim, the claim remains unclear to the Examiner.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 recites the phrase "conventional fillers". It is not clear to the Examiner as to what applicants mean by "conventional". Providing several examples of the fillers (with appropriate support in the specification) conventionally used in the industry would overcome this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 12, 19, 20 are rejected because the invention appears to employ novel microorganisms comprising novel vectors. Since the microorganisms are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed microorganisms are not fully disclosed, nor have all the sequences required for the construction of the vectors they carry have been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganisms. The specification does not disclose a repeatable process to obtain the microorganisms and it is not apparent if the DNA sequences of their vectors are readily available to the public. Accordingly, it is deemed that a deposit of these microorganisms should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that applicants have deposited the organisms under the terms of the Budapest Treaty, but there is no indication in the specification as to public availability. An affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

Claims 1-9, 22, 23, and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a xyloglucanase enzyme isolated from *P.polymyxa*, ATCC 832, or *P. sp.*, DSM 13329, *E.coli* DSM 13321, 13322 or a xyloglucanase encoded by the polynucleotide with SEQ ID NO:1, 3 or 5 or any DNA that hybridizes to the above DNA sequences under medium stringency conditions, does not reasonably provide enablement for any xyloglucanase isolated from any source and belonging to a family 44 of glycosyl hydrolases or any xyloglucanase from any source which exhibits a relative activity of 30% between pH 5 and 8, or any xyloglucanase isolated from any microorganism including fungi, bacteria such as gram positive bacteria, bacteria belonging to *Bacillus/Lactobacillus* subdivision, *Paenibacillus sp.* or any strain of *P.polymyxa* and yeasts. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the

prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-9, 22, 23, and 28 are so broad as to encompass any xyloglucanase isolated from any source including variants, mutants and recombinants . The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of xyloglucanases (including mutants, variants and recombinants) broadly encompassed by these claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only 3 enzymes (i.e., SEQ ID NO:1, 3, and 5).

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all xyloglucanases (as indicated above) and modifications and fragments of any xyloglucanase from any given source because the specification does not establish: (A) a rational and predictable scheme for isolation of the enzyme from any source; (B)regions of the protein structure which may be modified without effecting its activity; (B) the general tolerance of xyloglucanases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any xyloglucanase amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including all or any xyloglucanase isolated from any source including mutants, variants and recombinants with an enormous number of amino acid modifications. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of xyloglucanases having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 1-9, 22, 23, and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-9, 22, 23, and 28 are directed to xyloglucanases isolated from any source and belonging to a family 44 of glycosyl hydrolases or any xyloglucanase from any source which exhibits a relative activity of 30% between pH 5 and 8, or any xyloglucanase isolated from any microorganism including fungi, bacteria such as gram positive bacteria, bacteria belonging to *Bacillus/Lactobacillus* subdivision, *Paenibacillus sp.* or any strain of *P.polymyxa* and yeasts . Claims 1-9, 22, 23, and 28 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue that have not been disclosed in the specification. No description has been provided of the above polypeptide sequences encompassed by the claim. No information, beyond the characterization of three polypeptides encoded by polynucleotide sequences with SEQ ID NO:1, 3, or 5 has been provided by applicants which would indicate that they had possession of the above claimed genus of polypeptides. The specification does not contain any disclosure of the structure of all the polypeptide sequences, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of structure. Therefore many structurally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a three species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot

reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-8, 12, 19-20, 22-23, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulein et al. (WO 99/02663, Jan, 1999). This rejection is based upon the public availability of a printed publication. Claims 1-2, 5-8, 12, 19-20, 22-23, and 28 of the instant application is drawn to a xyloglucanase enzyme belonging to family 44 and exhibiting xyloglucanase activity of at least 30% between pH 5 and 8, wherein the enzyme is obtained from a microorganism, a gram-positive bacterium such as a *Paenibacillus* (It is recognized in the art that *Paenibacillus* are also known as *Bacillus*) belonging to *Bacillus/Lactobacillus* subdivision and wherein the enzyme is encoded by a DNA sequence which can hybridize to the DNA sequence with SEQ ID NO:1, 3 or 5 under medium stringency conditions and wherein the enzyme preparation comprises conventional fillers and further comprises one or more enzymes such as a protease, cellulase, lipase etc. Schulein et al. disclose a xyloglucanase having a

relative activity of more than 30% at pH 7 (which falls between pH 5 and pH 8), obtained from a gram-positive *Bacillus* belonging to the subdivision of *Bacillus/Lactobacillus*. Furthermore, as the enzyme is obtained from a *Bacillus sp.*, (and as applicants have not provided any specific method to characterize a xyloglucanase as belonging to family 44) Examiner also takes the position that the enzyme is encoded by a polynucleotide sequence that can hybridize with SEQ ID NO:1, 3 or 5 under moderately stringent conditions. The reference also discloses the enzyme preparation with conventional fillers and also as a mixture comprising other enzymes such as proteases, lipases cellulases etc. Therefore, Schulein et al. anticipate claims 1-2, 5-8, 12, 19-20, 22-23, and 28 as written.

Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald* et al., 205 USPQ 594.

Claims 1-4, 12, 19-20, 22-23, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Dalboege et al. (WO 94/14953, July, 1994). This rejection is based upon the public availability of a printed publication. Claims 1-4, 5-8, 12, 19-20, 22-23, and 28 of the instant application is drawn to a xyloglucanase enzyme belonging to family 44 and exhibiting xyloglucanase activity of at least 30% between pH 5 and 8, wherein the enzyme is obtained from a microorganism, such as a fungus and wherein the enzyme is encoded by a DNA sequence

which can hybridize to the DNA sequence with SEQ ID NO:1, 3 or 5 under medium stringency conditions and wherein the enzyme preparation comprises conventional fillers and further comprises one or more enzymes such as a protease, cellulase, lipase etc. Dalboege et al. disclose a xyloglucanase (EG III) isolated from a fungus having a relative activity of more than 30% at pH between pH 5 and 8 (see figure 3). Furthermore, as the enzyme is obtained from a fungus and as applicants have not provided any specific method to characterize a xyloglucanase as belonging to family 44, Examiner also takes the position that the enzyme belongs to family 44 and is encoded by a polynucleotide sequence that can hybridize with SEQ ID NO:1, 3 or 5 under moderately stringent conditions. The reference also discloses the enzyme preparation with conventional fillers and also as a mixture comprising other enzymes such as pectin lyases, pectate lyases and pectin methyl esterase etc. (see claim 20). Therefore, Dalboege et al. anticipate claims 1-4, 5-8, 12, 19-20, 22-23, and 28 as written.

Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald* et al., 205 USPQ 594.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-2, 5-8, 12, 19-20, 22-23, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Schulein et al. (US 6,268,197 B1, Jul 31, 2001, filed Jul. 1998). This rejection is based upon the public availability of a patent. Claims 1-2, 5-8, 12, 19-20, 22-23, and 28 of the instant application is drawn to a xyloglucanase enzyme belonging to family 44 and exhibiting xyloglucanase activity of at least 30% between pH 5 and 8, wherein the enzyme is obtained from a microorganism, a gram-positive bacterium such as a *Paenibacillus* (It is recognized in the art that *Paenibacillus* are also known as *Bacillus*) belonging to *Bacillus/Lactobacillus* subdivision and wherein the enzyme is encoded by a DNA sequence which can hybridize to the DNA sequence with SEQ ID NO:1, 3 or 5 under medium stringency conditions and wherein the enzyme preparation comprises conventional fillers and further comprises one or more enzymes such as a protease, cellulase, lipase etc. Schulein et al. disclose a xyloglucanase having a relative activity of more than 30% at pH 7 (which falls between pH 5 and pH 8), obtained from a gram-positive *Bacillus* belonging to the subdivision of *Bacillus/Lactobacillus*. Furthermore, as the enzyme is obtained from a *Bacillus sp.*, (and as applicants have not provided any specific method to characterize a xyloglucanase as belonging to family 44) Examiner also takes the position that the enzyme is encoded by a polynucleotide sequence that can hybridize with SEQ ID NO:1, 3 or 5 under moderately stringent conditions. The reference also discloses the enzyme preparation with conventional fillers and also as a mixture comprising other enzymes such as proteases, lipases cellulases etc. Therefore, Schulein et al. anticipate claims 1-2, 5-8, 12, 19-20, 22-23, and 28 as written.

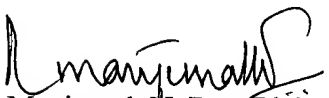
Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald* et al., 205 USPQ 594.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N Rao whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.



Manjunath N. Rao, Ph.D.
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September 5, 2002